

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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ROTEM COHEN, et al.,

Plaintiffs,

-against-

KITOV PHARMACEUTICALS HOLDINGS,  
LTD., et al.,

Defendants. :  
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17 Civ. 0917 (LGS)

**OPINION AND ORDER**

LORNA G. SCHOFIELD, District Judge:

Lead Plaintiffs Rotem Cohen and Jason Breuning, individually and on behalf of all other persons similarly situated, bring this putative class action against Defendants Kitov Pharmaceuticals Holdings, Ltd. (“Kitov”), Isaac Israel and Simcha Rock, alleging violations of § 10(b) and § 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”). Defendants move to dismiss the First Amended Complaint (the “Complaint”) pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the motion is granted in part and denied in part.

**I. BACKGROUND**

The following facts are taken from the Complaint and accepted as true for the purposes of this motion. *See Doe v. Columbia Univ.*, 831 F.3d 46, 48 (2d Cir. 2016).

**A. Facts**

Kitov is an Israeli clinical stage biopharmaceutical company that develops combination drugs for the simultaneous treatment of pain caused by osteoarthritis and hypertension. Plaintiffs purchased Kitov American Depositary Shares (“ADS”) during the relevant period, which is from

November 20, 2015 to February 6, 2017 (the “Class Period”). Because its ADS’s are traded on the NASDAQ, Kitov is a Securities Exchange Commission (“SEC”) reporting company.

Defendants Israel and Rock have been Kitov’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), respectively, throughout the Class Period. Defendants Israel and Rock both directly participated in the company’s management and its day-to-day operations, signed the Registration Statement and approved statements made in the various SEC filings at issue. During the Class Period, Kitov engaged at most ten employees and consultants.

Kitov’s lead drug candidate is KIT-302, a fixed dosage combination product based on two generic drugs designed respectively to treat pain and hypertension. Kitov must obtain Food and Drug Administration (“FDA”) approval of KIT-302’s New Drug Application (“NDA”) to commercialize the drug successfully. Under the shareholder rights agreement, Kitov shareholders were to receive additional Kitov shares if a “Milestone” was achieved by November 11, 2015. The Milestone is reached when “the pivotal clinical trial has been completed, the data have been analyzed, and the data analyses have demonstrated that the reduction in blood pressure in the group treated with the Kitov drug KIT-302 was at least half of that achieved with amlodipine monotherapy.” This Milestone is the same as the KIT-302 trial’s primary endpoint.

To facilitate FDA approval, Kitov agreed to a Special Protocol Assessment (“SPA”) with the FDA. The SPA required Kitov to conduct the Phase 3 trial (the “Study”) as provided in the SPA, including the design, subject inclusion criteria, minimum number of subjects, clinical endpoints and specific statistical analyses. Pursuant to the SPA, in September 2015, Kitov’s board of directors appointed an independent Data Monitoring Committee (“DMC”) to evaluate whether the Study showed sufficient efficacy for the NDA, and if not, whether additional patients were needed to achieve a statistically valid result for the NDA.

On November 17, 2015, Defendants provided the Study results to the DMC, which determined, on December 15, 2015, that the Study had met its primary endpoint for efficacy and did not require additional patients to be studied. Upon the DMC's finding, Defendant Rock obtained warrants to purchase additional Kitov shares.

In reality (according to the Complaint), as "corroborated by several former employees of Kitov," the actual Study results were falsified prior to submission to the DMC to improve the blood pressure data of patients who had received treatment. The actual, undisclosed results failed to provide statistically significant evidence of efficacy and did not show that the Study had met its primary endpoint.

On February 6, 2017, the Israeli publication *Calcalist* reported that Defendant Israel had been arrested and questioned by the Israel Securities Authority ("ISA") on suspicion of publishing misleading information in Kitov's July 2016 Prospectus filed with the SEC, among other filings, regarding the conclusions reached by the DMC. The same article stated that, according to the ISA, the misleading statements were made with the knowledge of Defendant Israel. On February 7, 2017, Kitov issued a press release that announced that the ISA had launched a formal investigation into the company's public disclosures concerning KIT-302, but maintained that it "stands fully behind the validity of all of its clinical trial results" and that it "continues to move forward toward the filing of [its] New Drug Application for KIT-302 with the FDA."

On February 6, 2017, when the *Calcalist* article was published, the price of Kitov's ADS fell \$0.33 per share, or 11.46%, to close at \$2.55 per share. On February 7, 2017, NASDAQ halted trading in Kitov's ADSs and warrants. When trading resumed on February 9, 2017, the

ADS price fell \$0.36 per share, or 14%, to close at \$2.19, and the warrant price fell \$0.27 per warrant, or 30%, to close at \$0.62 per warrant.

## **B. The Alleged Material Omissions and Misrepresentations**

The Complaint alleges a violation of § 10(b) of the Exchange Act based on material omissions and misstatements in the following documents that Kitov filed with the SEC: (1) a Registration Statement (Form F-1), filed November 20, 2015 (the “Initial Registration Statement”); (2) a Form 6-K, Ex. 99.2 press release, filed December 1, 2015; (3) a Form 6-K, Ex. 99.1 press release, filed December 15, 2015; (4) a second Form 6-K, filed December 15, 2015; (5) a Form 6-K, Ex. 99.2, filed January 11, 2016; (6) Kitov’s 2015 Annual Report (Form 20-F), filed March 16, 2016, and amended March 18, 2016; (7) Kitov’s Prospectus Supplement No. 1 (to the Prospectus dated March 18, 2016), dated May 16, 2016; (8) a Form 6-K, Ex. 99.1, Proxy Statement, filed May 24, 2016; (9) a Form 6-K, Ex. 99.1, Press Release, filed June 24, 2016; (10) a Registration Statement, filed June 27, 2016; (11) a Form 6-K, Ex. 99.1, Investor Presentation, filed September 7, 2016; (12) a registration statement (Form F-3) filed November 28, 2016.

The Complaint’s allegations of material omissions and misstatements fall into two categories. The first category -- which accounts for almost all of the alleged misleading statements -- comprises instances when Defendants failed to disclose that the Study results had been falsified. The Complaint alleges that as a result of this omission, public disclosures discussing the Study, the prospect of FDA approval and projected future costs and cash needs were misleading. For example, the Complaint alleges that the following statement from the December 15, 2015, Form 6-K, Ex. 99.1, Press Release was misleading without the disclosure that the Study results had been altered prior to their submission to the DMC: the Study results “demonstrated that the number of 152 patients treated was found to be adequate to provide

statistical validity and therefore, the results are final” and that “the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.”

The second category consists of two instances when Defendants allegedly implied that the Study results had not yet been delivered to the DMC, when in fact they had. For example, on November 20, 2015, the Initial Registration Statement stated, “You will experience further dilution if [by] November 11, 2015, we attain the milestone set forth in our 2013 Share Transfer Agreement pursuant to which we will issue 1,379,060 of our ordinary shares to the former shareholders of Kitov Pharmaceuticals.” The Initial Registration Statement also stated that, until “[t]he independent external [DMC] publish[es] its intermediate findings [of whether the Milestone set forth in the 2013 Share Transfer Agreement is met,] we will not be able to determine whether the milestone triggering the issuance of 1,389,060 of our ordinary shares was met.” These statements were made even though, as of November 17, 2015, “Kitov had already provided misleading clinical trial data to the DMC.”

## **II. STANDARD**

To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must “nudge[.]” claims “across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570. “To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient ‘to raise a right to relief

above the speculative level.” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). On a Rule 12(b)(6) motion, “all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff’s favor.” *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016).

“Any complaint alleging securities fraud must satisfy the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b) by stating with particularity the circumstances constituting fraud.” *Emp.’s Ret. Sys. of Gov’t of the V.I. v. Blanford*, 794 F.3d 297, 304 (2d Cir. 2015) (quoting *ECA, Local 134 IBEW Joint Pension Tr. Of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2008)). Under Rule 9, “[a] securities fraud complaint [based on misstatements] must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Charles Schwab Corp. v Bank of Am. Corp.*, No. 16 Civ. 1189, 2018 WL 1022541, at \*15 (2d Cir. Feb. 23, 2018) (internal quotation marks omitted) (quoting *Blanford*, 794 F.3d at 305). The PSLRA similarly requires a pleading to allege “the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all the facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1)(B). “A complaint may rely on information from confidential witnesses if they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” *Blanford*, 794 F.3d at 305 (internal quotation marks omitted).

### III. DISCUSSION

Plaintiffs assert a claim of securities fraud under § 10(b) of the Exchange Act and its implementing rule, Rule 10b-5. That rule makes it unlawful “[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5. The Complaint also asserts a claim of control person liability under § 20(a) of the Exchange Act.

Principally at issue on this motion is whether the Complaint sufficiently pleads three of the six elements of securities fraud -- a material misrepresentation or omission, scienter and loss causation.<sup>1</sup>

#### A. Section 10(b) Violation

##### 1. Material Omissions and Misrepresentations

The first element of a Rule 10b-5 violation is that the defendant made an omission or misstatement of material fact. “[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary ‘to make . . . statements made, in the light of the circumstances under which they were made, not misleading.’” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (quoting Rule 10b-5, 17 C.F.R. § 240.10b-5); accord *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239 (2d Cir. 2016) (“*Vivendi*”). “[O]nce a company speaks on an issue or topic, there

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<sup>1</sup> “To state a claim for violation of that provision, a plaintiff must allege ‘(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.’” *Charles Schwab Corp.*, 2018 WL 1022541, at \*14 (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2407 (2014)).

is a duty to tell the whole truth, even where there is no existing independent duty to disclose information on the issue or topic.” *Id.* at 258 (internal quotation marks omitted); *see also Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002) (when a party chooses to speak on a subject, it has a “duty to be both accurate and complete”).

A statement or omission is material when there is “a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available” to the market. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 390 (2d Cir. 2015) (internal quotation marks omitted). Because materiality is a mixed question of law and fact, a claim may not be dismissed on this ground unless the misstatements or omissions are “so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.” *Id.* (internal quotation marks omitted).

The PSLRA provides a safe harbor for forward-looking statements. *See* 15 U.S.C. § 78u-5(c). “[A] defendant is not liable if (1) the forward-looking statement is identified and accompanied by meaningful cautionary language, (2) the forward-looking statement is immaterial, *or* (3) the plaintiff fails to prove that the forward-looking statement was made with actual knowledge that it was false or misleading. Because the safe harbor is written in the disjunctive, a forward-looking statement is protected under the safe harbor if any of the three prongs applies.” *Vivendi*, 838 F.3d at 245–46 (internal quotation marks, modifications and citation omitted) (emphasis added). “To avail themselves of safe harbor protection under the meaningful cautionary language prong, defendants must demonstrate that their cautionary language was not boilerplate and conveyed substantive information.” *Slayton v Am. Express Co.*, 604 F.3d 758, 772 (2d Cir. 2010); *accord Vivendi*, 838 F.3d at 247.



A statement is not actionable if it is mere puffery. Puffery encompasses “statements that are too general to cause a reasonable investor to rely upon them, and thus cannot have misled a reasonable investor. They are statements that lack the sort of definite positive projections that might require later correction.” *Vivendi*, 838 F.3d at 245 (internal quotation marks, modifications and citations omitted).

**a. The Failure to Disclose that the Study Results were Falsified**

The Complaint adequately pleads that Defendants made material omissions when they made statements about the results of the Study -- including, for example, that the Study results “successfully met the primary efficacy endpoint of the trial protocol” -- but failed to disclose that the results had been falsified. This omission is material because it creates an impression that KIT-302 Phase 3 study results *actually* showed statistically significant efficacy, that the NDA for KIT-302 would likely be approved, and that Kitov, which relied on the success of KIT-302, would likely remain a successful company.

In contrast, omissions from statements that do not pertain to the Study’s findings are not actionable because the subject of the omissions and the subject of the statements are too attenuated. In that case, the omitted information is not “necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading.” *Matrixx*, 563 U.S. at 44 (emphasis in the original). For example, the Complaint alleges that a general description of the SPA in the Initial Registration Statement is misleading for failing to disclose that Kitov had already provided falsified clinical trial data to the DMC, with the nearly certain result that the FDA would not approve the NDA. The subject of the statement -- a general description of the SPA process -- and the subject of the omission -- falsified data -- are too unrelated for the omission to be actionable as to the statement made. In other words, there was

nothing inaccurate or incomplete about the description of the SPA process without the omitted facts, and consequently, there was no duty to disclose them when describing the process. *See, e.g., Plumbers & Steamfitters Local 137 Pension Fund v. Am. Express Co.*, No. 15 Civ. 5999, 2017 WL 4403314, at \*17 (S.D.N.Y. Sept. 30, 2017) (“[T]he statements cited by Plaintiff were not misleading. Accordingly, Defendants’ statements did not give rise to a duty to disclose.”); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 584 (S.D.N.Y. 2016) (finding that nondisclosure of the FDA’s decision was not actionable because Defendants never suggested otherwise).

Similarly, Defendants’ statements of plans and expectations if the FDA approves KIT-302 are not actionable because they are not misleading. For example, the Initial Registration Statement represents: “Upon and subject to receipt of the requisite approvals, we intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements . . . .” With the use of the term “subject to,” the statement of intent is expressly conditioned on receipt of FDA approval and does not express any opinion of the likelihood of such approval. As such, it is not misleading without further disclosure.<sup>2</sup>

Defendants argue that the failure to disclose falsified data is not an actionable omission in any instance because the results were not falsified. That argument is premature on a motion to dismiss, as long as the allegation of falsehood is sufficiently detailed under the heightened pleading standard of the PSLRA and Rule 9(b). *See Columbia Univ.*, 831 F.3d at 48 (finding that the facts from the Complaint are accepted as true for the purposes of a motion to dismiss). The Complaint here is sufficiently detailed. It quotes each statement alleged to be false in

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<sup>2</sup> These statements also may be inactionable as forward-looking statements and puffery. However, as they are not misleading, this Opinion does not address those issues. *Vivendi*, 838 F.3d at 245.

Kitov's SEC filings; each filing is fully identified by its name and the date filed with the SEC; and the Complaint explains why the statements were fraudulent -- that they failed to disclose or did not take into account that the Study results "failed to provide statistically significant evidence of efficacy . . . [and were] falsified prior to transmission to the DMC to improve the blood pressure data of patients who received treatment[, resulting] in the DMC incorrectly finding that the KIT-302 trial met its primary endpoint."

Defendants quote from the SEC filings at issue in the Complaint<sup>3</sup> to argue that the Study was conducted by independent research organizations, that Defendants would have no access to the data and therefore could not have tampered with the results. Although Defendants ultimately may be able to prove their point, unlike the letter in the *Gillis* case, the documents Defendants cite do not require the conclusion that the Study results were immune from Defendants' tampering. *Cf. Gillis*, 197 F. Supp. 3d at 582 (finding that "plaintiffs' core premise . . . is belied by the text of the letter itself" and relying instead on the actual statements made in the "No Agreement Letters" at issue). Moreover, the Complaint challenges the veracity of the very statements on which Defendants rely, including that "[t]he Company does not have and will not have access to this data until the test is completed by the Committee."

Defendants argue that the challenged statements are forward-looking and contain cautionary language such that they are not actionable under PSLRA. This argument is unavailing as to the statements found to be actionable above. They are limited to statements pertaining to the purported actual results of the Study, and such statements by definition are not

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<sup>3</sup> The Court may consider these documents on this motion to dismiss because they are the very documents at issue in the Complaint. "In adjudicating a motion to dismiss, a court may consider only the complaint, any written instrument attached to the complaint as an exhibit, any statements or documents incorporated in it by reference, and any document upon which the complaint heavily relies." *ASARCO LLC v. Goodwin*, 756 F.3d 191, 198 (2d Cir. 2014).

forward-looking. These statements similarly are not statements of corporate optimism or puffery, but instead are statements of historical fact.

### **b. The Alleged Timing Misstatement**

The Complaint's second category of alleged misstatements are two instances when Defendants allegedly misstated when the Study results were submitted to the DMC. These allegations fail to state a claim.

The Complaint alleges that Kitov falsely represented or implied in its Initial Registration Statement that the Study results had not yet been submitted to the DMC, when in fact they had. This assertion mischaracterizes the disclosures at issue. The first merely states that Kitov is unable to predict if and when the additional shares will be distributed, as the distribution depends on the DMC's assessment of the Study results. The second disclosure describes the SPA procedures and the DMC's role. Neither disclosure states whether the Study results have been provided to the DMC or when.

## **2. Loss Causation**

The Complaint sufficiently pleads loss causation.<sup>4</sup> “To plead loss causation, plaintiffs must allege “that the subject of the fraudulent statement or omission was the cause of the actual loss suffered.” *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 232 (2d Cir. 2014). “[I]t is enough that the loss caused by the alleged fraud results from the relevant truth leaking out.” *Vivendi*, 838 F.3d at 261 (internal quotation marks and alteration omitted). “Plaintiffs must show that a ‘misstatement or omission concealed *something* from the market

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<sup>4</sup> The Second Circuit has not resolved which pleading standard applies to the issue of loss causation -- the heightened pleading requirements of Rule 9(b) or the “short and plain statement of the claim” standard of Rule 8(a)(2). *Acticon AG v. China N.E. Petroleum Holdings Ltd.*, 692 F.3d 34, 37–38 (2d Cir. 2012). In this case, the Complaint satisfies both standards.

that, *when disclosed*, negatively affected the value of the security.’” *Id.* at 261–62 (quoting *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005) (alterations and internal quotation marks omitted) (emphasis in original). “Whether the truth comes out by way of a corrective disclosure describing the precise fraud inherent in the alleged misstatements, or through events constructively disclosing the fraud, does not alter the basic loss-causation calculus.” *Vivendi*, 838 F.3d at 262. “Plaintiffs need not demonstrate on a motion to dismiss that the corrective disclosure was the *only* possible cause for decline in the stock price.” *Carpenters Pension*, 750 F.3d at 233 (emphasis in original). In other words, a complaint can sufficiently plead loss causation without alleging facts that disaggregate losses or that rule out other causes.

The Complaint plausibly pleads that Plaintiffs purchased Kitov securities at an inflated price, which fell significantly when Kitov’s alleged misleading statements about the Study were reported in a news article describing an Israeli regulatory investigation. The Complaint alleges that on February 6, 2017, the Israeli publication *Calcalist* reported that the ISA had questioned Defendant Israel on suspicion of publishing misleading information about the clinical trial of KIT-302. The article also stated that the ISA had found that Kitov -- with Israel’s knowledge -- had made misleading statements in securities filings in December 2015 and July 2016. The Complaint alleges that on February 6, 2017, immediately after publication of the article, the price of Kitov’s ADSs fell \$0.33 per share, or 11.46%, and the price of Kitov’s warrants fell \$0.10 per warrant or 10%. The next day, February 7, 2017, the NASDAQ halted trading in Kitov’s securities before the market open, and Kitov issued a press release confirming that the ISA had commenced a formal investigation. Kitov’s statement in the press release that it stood by its earlier disclosures about KIT-302 and was on track with its NDA approval does not change the

analysis. When trading resumed two days later, on February 9, 2017, Kitov's ADS price fell another \$0.36 or 14%, and Kitov's warrant price fell another \$0.27 or 30%.

These allegations are sufficient to plead loss causation. They allege facts that, if true, show that the falsification of the Study was concealed from the market, and that the disclosure of the company's misleading statements about the Study negatively affected the value of the company's securities. *See Vivendi*, 838 F.3d at 261–62. In this case, disclosure of the Israeli regulatory investigation is sufficient to plead loss causation. *See In re New Oriental Educ. & Tech. Grp. Sec. Litig.*, 988 F. Supp. 2d 406, 428 (S.D.N.Y. 2013) (“[D]isclosure of an SEC investigation into a particular business practice can be sufficient to allege loss causation with respect to alleged misstatements regarding that practice” even without an admission of wrongdoing); *Plumbers & Pipefitters Nat’l. Pension Fund v. Orthofix Int’l N.V.*, 89 F. Supp. 3d 602, 620 (S.D.N.Y. 2005) (“[C]ourts within this District have concluded that the disclosure of an investigation into a particular business practice can be sufficient to allege loss causation with respect to alleged misstatements regarding that practice.”) (internal quotation marks omitted) (collecting cases); *see also, e.g., Vivendi*, 838 F.3d at 263 (regarding claims of alleged concealment of liquidity risk, finding loss causation based on news reports of: a French regulatory investigation of possible securities fraud, rating agency downgrades, consummated and planned sales of corporate assets and the company's acknowledgment of short-term liquidity problems).

### **3. Scienter**

The Complaint sufficiently pleads scienter as to Defendant Israel but not Defendant Rock. Consequently, the § 10(b) claim against Defendant Rock is dismissed.

The PSLRA requires a plaintiff to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). “This standard requires courts to take into account ‘plausible opposing inferences.’” *Matrixx*, 563 U.S. at 48 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007)). “For an inference of scienter to be strong, ‘a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.’” *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alterations and emphasis in original). In making this determination, a court must review “all the allegations holistically.” *Tellabs*, 551 U.S. at 326.

A plaintiff may satisfy the scienter requirement by “alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness.” *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015) (quoting *ATSI*, 493 F.3d at 99). Conscious misbehavior “requires a showing of deliberate illegal behavior,” *Gould v. Windstar Commc’ns, Inc.*, 692 F.3d 148, 158 (2d Cir. 2012) (internal quotation marks and citation omitted), whereas recklessness includes “conscious recklessness” or “a state of mind approximating actual intent, and not merely a heightened form of negligence,” *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009); accord *Fries v. N. Oil & Gas, Inc.*, No. 16 Civ. 6543, 2018 WL 388915, at \*8 (S.D.N.Y. Jan. 11, 2018). A plaintiff adequately pleads recklessness by alleging that the defendant: (1) knew facts or had access to information contradicting its public statements; or (2) failed to review or check information that it had a duty to monitor. *Blanford*, 794 F.3d at 306. “[W]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information.” *Teamsters Local 445 Freight*

*Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (internal quotation marks omitted); *accord Fries*, 2018 WL 388915, at \*10.

A complaint may satisfy the scienter requirement as to a corporation “by pleading facts sufficient to create a strong inference either (1) that someone whose intent could be imputed to the corporation acted with the requisite scienter or (2) that the statements would have been approved by corporate officials sufficiently knowledgeable about the company to know that those statements were misleading.” *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015) (internal quotation marks omitted).

**a. Defendant Rock**

The Complaint does not sufficiently plead Defendant Rock’s scienter. The only allegations concerning Rock are that: he was Kitov’s CFO at all relevant times and signed the Registration Statement; he must have known of the fraud, allegedly perpetrated by Israel, because Kitov had at most ten employees during the Class Period; and he had a motive to hide the fraud because he obtained warrants to purchase additional shares of Kitov stock when the company met the primary endpoint of the KIT-302 trial.

Taken together, the Complaint's allegations do not support a cogent inference of scienter that is “at least as compelling as any opposing inference one could draw from the facts alleged.” *Tellabs*, 551 U.S. at 324. While the additional warrants may have provided Rock with a motive to hide the fraud had he known about it, nothing in the Complaint suggests that he knew or should have known that the Study data was falsified. The size of the company does not give rise to a “strong inference” that Rock acted with a guilty state of mind. The allegations taken as a whole do not imply that he knew about the fraud, had access to information about it, or failed to check information he had a duty to monitor. *See Fries*, 2018 WL 388915, at \*10 (“To state a



claim based [on] recklessness, plaintiffs may either specifically allege defendants' knowledge of facts or access to information contradicting defendants' public statements, or allege that defendants failed to check information that they had a duty to monitor.") As CFO, rather than the head of research or product development, for example, the scope of his duties would not naturally encompass the Study and its results. The more compelling inference from the limited allegations in the Complaint is that Israel hid the fraud from other employees, including Rock. The securities fraud claim against Rock is therefore dismissed. *Accord In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 406 (S.D.N.Y. 2016) (finding that the defendants' access to quarterly brief on corporate compliance, participation on the compliance committee and access to the whistleblower investigation are insufficient to establish strong circumstantial evidence that defendants knew facts or had access to information suggesting that their public statements were inaccurate).

#### **b. Defendant Israel**

The Complaint sufficiently pleads that Israel acted with scienter. The Complaint alleges that Israel was Kitov's CEO throughout the Class Period and signed the Registration Statement. He directed that the Study be falsified prior to its submission to the DMC to improve the results of patients treated with KIT-302, which led to the DMC's erroneous finding that the Study met its primary endpoint. At the time that the Study data was falsified, Israel was one of only two full-time Kitov employees. The *Calcalist* article reported, and a Kitov press release confirmed, that the ISA had launched a formal investigation in connection with Kitov's SEC filings related to KIT-302. The article further stated that, according to the ISA, Defendant Israel knew that the statements were misleading.

Critical to the finding of scienter is the Complaint's reliance on several former Kitov employees for the allegations that Israel had falsified the Study data. The Complaint alleges that this allegation was "corroborated by several former employees of Kitov," which at any given time never engaged more than ten people as employees and consultants; and that "according to several former consultants of Kitov with knowledge of the clinical trial results, Israel was the individual who directed that the . . . data be falsified to show efficacy . . . ." Plaintiffs' reliance on unidentified sources does not undermine allegations against Defendant Israel. Confidential sources are not required to be named "provided they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Inv. Tech. Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d 596, 623 (S.D.N.Y. 2017) (citing *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)). "[P]laintiffs who rely on confidential sources are not always required to name those sources, even when they make allegations on information and belief concerning false or misleading statements." *Novak*, 216 F.3d at 313. Requiring disclosure of confidential sources could deter them from providing information "or invite retaliation against them." *Id.* at 314.

Here, the confidential sources are described as "former consultants of Kitov with knowledge of the clinical trial results." While this description might not suffice in an organization with hundreds of employees, any more detailed description in this case likely would reveal the identity of the source. This evidence from multiple former consultants, combined with Israel's position as CEO in a small organization and news of the Israeli regulatory investigation, give rise to a plausible inference, at least as compelling as any other, that Israel was responsible for the falsification of data and therefore had actual knowledge that his statements about the successful completion of the Study were false.

### **c. Corporate Scierter**

Because the Complaint adequately alleges scierter as to Defendant Israel, Kitov's CEO, Kitov's scierter is inferred from Defendant Israel's scierter. *See Teamsters*, 531 F.3d at 195 (“[T]he most straightforward way to raise [an inference of requisite scierter] for a corporate defendant will be to plead it for an individual defendant” whose intent can be imputed to the corporation).

### **B. Section 20(a) Violation**

Section 20(a) imposes joint and several liability on control persons for underlying violations of the Exchange Act. *See* 15 U.S.C. 78t. To state a claim under § 20(a), a plaintiff must allege both a primary violation of the Exchange Act and control over the primary violator. *See Carpenters Pension*, 750 F.3d at 236. Defendants' main argument for dismissal of this claim is that the primary claim fails, so the secondary liability claim must fail as well. As the Court has denied Defendants' motion to dismiss the § 10(b) claim, and Plaintiffs have otherwise adequately alleged control person liability, the motion to dismiss Plaintiff's Section 20(a) claim is denied.

### **C. The Parties' Letters**

On September 20, 2017, Defendants filed a letter stating that the Complaint should be entirely dismissed based on statements made on a public message board, where Ameya Pilgaonkar stated that he did not consent to being a named plaintiff in this action. This application is denied for two reasons. First, on February 7, 2017, Mr. Pilgaonkar filed a certification, which states that he “has reviewed the complaint and authorized its filing” and which bears his signature. This document outweighs the unverified online postings on which Defendants rely. Second, on June 15, 2017, the Court appointed Rotem Cohen and Jason

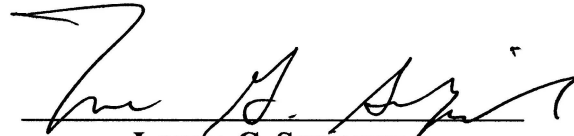
Breuning as Lead Plaintiffs, and the caption of the First Amended Complaint, filed on June 19, 2017, no longer names Mr. Pilgaonkar as Plaintiff. Consequently, his prior consent is no longer pertinent to the Complaint.

#### **IV. CONCLUSION**

For the foregoing reasons, Defendants' motion to dismiss is GRANTED in full as to Defendant Rock and GRANTED as to statements that do not pertain to the Study's actual historical findings, but otherwise DENIED as to Defendants Israel and Kitov. Specifically, claims based on the allegations in the following paragraphs are dismissed: 29-40, 63-64, 78-79.

The Clerk of Court is respectfully directed to close the motion at Docket Numbers 33 and 46, and remove from the docket Simcha Rock as a Defendant and Ameya Pilgaonkar as a Plaintiff.

Dated: March 20, 2018  
New York, New York



**LORNA G. SCHOFIELD**  
**UNITED STATES DISTRICT JUDGE**